

Permitting decisions

Bespoke permit

We have decided to grant the permit for Pharmaron UK Hoddesdon Site operated by Pharmaron UK Limited. The permit number is EPR/AP3933QP/A001.

We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that the appropriate level of environmental protection is provided.

Purpose of this document

This decision document provides a record of the decision making process. It:

- highlights [key issues](#) in the determination
- summarises the decision making process in the [decision checklist](#) to show how all relevant factors have been taken into account
- shows how we have considered the [consultation responses](#).

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Read the permitting decisions in conjunction with the environmental permit. The introductory note summarises what the permit covers.

Key issues of the decision

1. Extent and nature of the facilities at the site and the permitted activities

1.1 Defining the limits of the main pharmaceutical production activity and the status of the Fleming building commercial research and development activity

The site was previously owned by Merck Sharpe & Dohme (MSD) and operated as a pharmaceutical research and development facility outside of the environmental permitting regime. Since purchase of the site from MSD in 2016, the applicant (now the operator) has recommissioned the Fleming building for performance of laboratory scale commercial research and development and the Pharmaron Research Preparative Laboratory (PRPL) facility for pilot-plant scale commercial research, development and active pharmaceutical ingredients (API) production. The applicant initially proposed to further develop the Fleming building research and development facility with the intention to facilitate future commercial production of API in this building. During the determination of this permit application, the applicant decided to:

- restrict all commercial production of API to the PRPL facility; and
- limit production of API under commercial research and development projects within the Fleming building to gramme scale with maximum output of less than 20 kg per single product per annum.

The production of API within the PRPL facility meets the definition of production of pharmaceuticals set out in the Environment Agency's Regulatory Guidance Note 2 (RGN 2) guidance and this activity has been included in the permit as Schedule 4.5 Part A(1)(a) Producing pharmaceutical products. The applicant proposes to produce up to a total of 1,000 kg of API per annum within the synthesis modules and the hydrogenator reactor associated with the PRPL facility. Production will be in batches from 1 kg up to 40 kg per batch. Under the Environment Agency MPP guidance report reference GEHO0511BTUN-E-E, we have retained the aggregated activity threshold applied under the discontinued OPRA scheme to allow an aggregate of 250 tonnes per annum production under one Schedule 1 S4.5 Part A(1)(a) activity. As the aggregated production of API from the various PRPL synthesis units is less than 1,000 kg per annum, we have decided that there is one Schedule 1 activity – S4.5 Part A(1)(a) *Producing pharmaceutical products*. The permit limits this activity to production of API under a multi-product protocol (MPP) in multi-purpose plants located in the PRPL facility with a maximum output of 1,000 kg/annum. The PRPL facilities are:

- three large scale PRPL synthesis modules having maximum combined reactor vessel capacities of 1560, 1560 and 960 litres with maximum individual reactor vessel capacity of 1000, 1000 and 400 litres respectively;
- one small scale PRPL process chemistry support area;
- one PRPL hydrogenation module comprising a single reactor vessel with maximum capacity 400 litres;
- two preparative laboratories used to undertake commercial research and development associated with API production within the PRPL facility using pilot plant scale glassware with a maximum capacity of 70 litres; and
- an enclosed automated fixed milling system (the Alpine Mill) located within the PRPL facility used for preparation of certain dry raw materials in with maximum throughput 100 kg/hr.

The research and development activities within the Fleming building use laboratory scale equipment with production of API at gramme scale. We have decided that the Fleming building activity is not part of the stationary technical unit (STU) for the main Part 4.5 activity and that this main activity is limited to the PRPL facility. We have made this decision based on the Fleming building operations being distinctly different from the PRPL facility operations in terms of scale and equipment and there being no process link between the facilities.

In line with RGN 2 guidance, we have not included the Fleming building operations as a separate STU and the operations are therefore not included in the permit as a separate Schedule 4.5 Part A(1)(a) pharmaceutical production activity. We have made this decision based on the projected maximum single product production within the Fleming building being significantly lower than the 20 kg per year threshold for consideration as an EPR scheduled pharmaceutical production activity provided in Appendix 1 of RGN 2.

In so far as the knowledge and experience gleaned from the research and development activity conducted within the Fleming building is used to develop the processes used in the PRPL facility, the Fleming building activity supports the main Part 4.5 activity within the PRPL facility. We have therefore included the Fleming building commercial research and development activity in the permit as a directly associated activity (DAA).

The status of the Fleming building operations as a DAA within the permit ensures that the activities must be managed to best available techniques (BAT) standards for the installation. The permit requires control of the projected emissions from the Fleming building to the levels assessed in the application H1 risk assessment for emissions to air. Emissions from the Fleming building must be controlled through operating techniques listed in table S1.2 of the permit, including: limiting the short and long term consumption rates of raw materials to the levels included in the impact assessment.

The applicant is in the process of extending the commercial research and development facilities within the Fleming building which will involve installation of additional laboratory fume hoods on the second and third floors of the building with new stack emission releases to atmosphere. Projected emissions from both the existing and extended Fleming building facilities have been included within the envelope of assessed emissions from the installation and the permit therefore allows emissions from the new fume hood vents as described in the application.

1.2 Defining the status of the on-site effluent treatment plant activity

There is an existing on-site effluent treatment plant (ETP) which is designed to allow balancing and neutralisation of trade effluent prior to discharge to sewer under a Trade Effluent Consent issued by Thames Water. The ETP neutralisation process is not currently in use however the permit allows for the re-instatement of the process subject to delivery of a pre-operational condition (see the Pre-operational conditions sub-section of the key issues section). We have included this activity within the permit as a Schedule 1 activity – S5.4 Part A(1)(a)(ii) *Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day involving physico-chemical treatment*. We have included this activity within the permit as a scheduled activity rather than a DAA as the applicant proposes to re-instate the neutralisation system with the potential to treat and release more than 50 tonnes per day of effluent to sewer.

We have limited the scope of the on-site ETP activity to cover treatment of non-hazardous aqueous waste streams arising from the PRPL facility and the Fleming buildings directed to the ETP by the segregated Trade Effluent system for pH adjustment prior to discharge to sewer under a Trade Effluent Consent issued by Thames Water.

The current Trade Effluent Consent was granted by Thames Water during the period when the site was under ownership of MSD and allows a maximum discharge of 250 m³ per 24 hr period, a maximum throughput of 63 m³/hr and the discharge of a wide range of pollutants including solvents and metal species. The applicant has committed to varying this consent to reduce the maximum flow and limit the range of pollutants to better represent the activities presented in the permit application EPR/AP3933QP/A001 and assessed in their application H1 risk assessment (EHS-HOD-007 surface water pollution risk assessment).

The applicant's application H1 risk assessment EHS-HOD-007 is a surface water pollution risk assessment performed in accordance with our online guidance for the proposed discharge to sewer (<https://www.gov.uk/guidance/surface-water-pollution-risk-assessment-for-your-environmental-permit>). To reflect the scope of this risk assessment, we have added limits to table S3.3 of the permit. We have:

- limited the discharge rate to a maximum annual average of the daily average discharge rate of 90 m³/day period;
- restricted the hazardous substances which may be emitted to dissolved copper and zinc only; and
- set more stringent emission limit values for these substances than required by the existing Trade Effluent Consent.

We have reviewed the applicant's H1 risk assessment and confirmed that at the ELVs we have set for dissolved copper and zinc and the maximum annual average discharge rate set in table S3.3 of the permit, there will be no risk of significant impacts in the receiving surface waters.

1.3 Issues associated with the current and potential future status of other Directly Associated Activities included within the permit

In so far as the following supporting utilities support the main site activities, we have included the operation of these utilities as DAAs within the permit:

- pre-treatment of raw materials (water);
- storage and use of liquefied gases (liquid nitrogen);
- PRPL facility heat transfer system;
- compressed air system;
- PRPL vacuum system;
- storage of wastes generated within the installation;
- surface and storm water management;
- firewater management; and
- emergency power.

The limits of these activities are as described in table S1.1 of the permit. Issues associated with the current and future status of the combustion plant associated with emergency power generation are discussed below.

Emergency power generation for use by the activities included in the permit is provided by two diesel-fuelled generators located beside the Fleming and Utilities buildings with net rated thermal inputs of 0.58 MWth and 1.96 MWth respectively. It is noted that the generators are currently used to provide power to the site during emergencies only and tested for no more than 50 hours per year. These generators are 'excluded generators' with respect to the Environmental Permitting (England and Wales) Regulations (EPR) 2018.

The Utilities building generator, having a rated thermal input equal to or less than 5 MW and greater than 1 MW, is a medium combustion plant which is required to be included within a suitable EPR permit from 01/01/29. The Fleming building generator, having a net rated thermal input of less than 1 MW, is not a medium combustion plant and is not required to be included in a suitable EPR permit.

If the applicant proposes to enrol the generators in a balancing service agreement or use to provide demand side management, including Triad avoidance, the status of the generators may change to that of 'specified generators' and require a variation to the permit by 01/01/30 to meet standards for specified generators described in Schedule 25B of EPR 2018.

1.4 Site facilities which are excluded from the installation

The installation boundary surrounds the entire site and excludes certain buildings which are leased to the previous site owner (MSD) for non-EPR related activities: the Sigal building, the Hilleman building, the cafeteria and the multi-story car park. The Pharmaceutical Operations and Archive buildings are also excluded from the installation as no EPR related activities are currently performed in these buildings. The applicant has indicated that they may wish to conduct scheduled activities or directly associated activities within these buildings in future and, in this event, will be required to submit an application to vary the permit.

There are a number of combustion plant on the site which are not included within the permit as the outputs from the plant are not currently used to support the permitted activities. The plant which are not included in the permit are:

- two boilers located in the Fleming building each with a net rated thermal input of 3.15 MWth;
- two boilers located in the Utilities building each with a net rated thermal input of 4.57 MWth; and
- two emergency generators associated with the Sigal and cafeteria buildings with estimated net rated thermal inputs of 0.49 MWth and 0.61 MWth respectively.

As medium combustion plant with net rated thermal inputs equal to or less than 5 MW and greater than 1 MW, the boilers must be included within a suitable EPR permit from 01/01/29.

If the two emergency generators continue to be used as described in the permit application documents i.e. as back-up generators for use to provide power to the site during emergencies only and tested for no more than 50 hours per year, their status with respect to EPR 2018 will remain as 'excluded generators'. As the generators have estimated net rated thermal inputs of less than 1 MW, the units are not medium combustion plant and should not require to be included within an EPR permit.

If the applicant proposes to enrol the generators in a balancing service agreement or use to provide demand side management, including Triad avoidance, the status of the generators will change to that of 'specified generators' under EPR 2018. In this event, the units will be required to be included in a suitable EPR permit, and require suitable emissions abatement for continued use, from 01/01/30.

In the event that the applicant wishes to use the currently 'moth-balled' pharmaceutical manufacturing plant within the Pharmaceutical Operations and Archive building, there may be a requirement to vary the permit to include the boilers within the Utilities building as a DAA. This is based on indications by the applicant that the Utilities building boilers are likely to be used to support activities in the Pharmaceutical Operations and Archive building.

1.5 Status of installation activities with respect to Schedule 14 of the EPR regarding solvent emissions activities

Based on the information provided by the applicant in section 30.1 of the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5, we are satisfied that the installation is not an EPR Schedule 14 Solvent Emission Activity. The applicant has demonstrated that the consumption of solvents at the installation at the Maximum Operational Throughput (MOT) scenario does not exceed the threshold of 50 tonnes per annum for manufacturing of pharmaceutical products defined in Annex VII of the Industrial Emissions Directive 2010/75/EU (IED). The calculation of solvent consumption is in keeping with the definition within Annex VII of the IED and takes into account the quantity of solvents recovered for production of secondary liquid fuels off-site. The applicant has provided evidence that this recovery process falls under an R3 Recovery code as defined in Annex II of the European Waste Framework Directive 2008/98/EC. Although the installation is not an EPR Schedule 14 Solvent Emission Activity, the applicant has committed to managing solvents to minimise emissions of VOCs in accordance with BAT for the manufacturing of pharmaceutical products and has specifically committed to compliance with the waste gas emission limit value of 20 mgC/m³ as set out in Annex VII of the IED. In view of the reliance of the process control systems within the PRPL facility on the continuous emissions monitoring system for VOC emissions and the applicant's commitment to meet the IED limit, we have incorporated this emission limit value into the permit in table S3.1. The applicant has also committed to meeting the total emission limit value of 5% of solvent input as set out in Part 2 of Annex VII of the IED. We have not included this commitment as an emission limit within the permit as the IED requires compliance either with the waste gas emission limits or the total emission limit to demonstrate BAT. We have however required the applicant to report performance against the 5% total emission limit target on an annual basis.

2. Operational controls, emission limits and conditions applied to protect biodiversity, heritage, landscape and nature conservation

We have assessed the application and its potential to affect all known sites of nature conservation, landscape and heritage and/or protected species or habitats identified in the nature conservation screening report as part of the permitting process. The sites within our screening distances for emissions are identified in the following sub-sections along with a description of the operational controls, emission limits and conditions which have been placed in the permit to protect these ecological receptors. The restrictions included within the permit ensure that emissions to air are insignificant and emissions to sewer are unlikely to have significant impact on the ecological receptors included in our assessment. We have not consulted Natural England on the application. The decision was taken in accordance with our guidance.

2.1 Emissions to air

Emissions to air arise from point sources associated with: the operations within the PRPL facility; the Fleming building; and, from testing and emergency use of the two diesel fuelled emergency generators. There are no significant fugitive emissions sources. Point source emissions from the PRPL facility are: the abated emissions from the synthesis modules and laboratories by way of the 30.0 m high PRPL process stack (reference A1); the abated emissions from the reactor vessel atmospheric vent headers by way of the 20.5 m high vent header stacks (references A2-4); the unabated emissions from the PRPL hydrogenation module by way of the 20.5 m high reactor vent (reference A5); and, the unabated general area air emissions from each of the synthesis modules by way of the four 20.5 m high general area heating, ventilation and air conditioning (HVAC) unit vents (references A6-A9). Point source emissions from the Fleming building are the abated emissions from the research and development activities performed within the existing and proposed laboratory fume cupboards and released by way of the existing and proposed fume hood vent clusters: existing 27.0 m high vent cluster (references A10-A13); and, proposed 27.7 m high vent cluster (references A14 and A15). Potential emissions to air consist of a wide range of volatile organic compounds (VOCs), inorganic reagents and particulate matter used in the API research, development and production activities, emissions of produced API and combustion gas emissions from the emergency generators. Emissions to air from the main PRPL process stack (A1) are subject to continuous emissions monitoring (CEMS) to for total carbon.

We have assessed the potential for the applicant's activities to release emissions to air which may impact on all ecological receptors within our screening distance. Our assessment indicates that the emissions to air associated with both the maximum and expected operational throughput (MOT and EOT) scenarios are insignificant with respect to ecological receptors in terms of both air quality and deposition impacts. In

reaching this conclusion, we have taken into account the specific sensitivities of the ecological receptors including the presence of ammonia sensitive lichens at several sites. We have restricted emissions to air to the emission levels proposed and assessed by the applicant in their assessment of emissions to air (EHS-HOD-002 Environmental Assessment for Hoddesdon V5) i.e. to the levels associated with the assessed envelope of emissions for the MOT scenario. We have restricted emissions to these levels through the permit by setting operational controls, emission limits and the multi-product protocol (MPP) condition as described in the following sub-sections.

2.1.1 Ecological receptors for air emissions

The following ecological receptors are within our screening distance for emissions to air from the site and have been included in the assessment of the impacts of the proposed activities on ecological receptors. These are:

- Wormley-Hoddesdonpark Woods Special Area of Conservation (SAC)
- Lee Valley Special Protection Area (SPA)
- Lee Valley Special Protection Area Ramsar
- Hertford Heath Site of Special Scientific Interest (SSSI)
- Rye Meads SSSI
- Wormley-Hoddesdonpark Woods North SSSI
- Broxbourne Woods National Nature Reserve (NNR) and
- Broxbourne Woods Local Wildlife Site (LWS)
- Hailey Wood LWS
- Golding's Wood (Hertford Heath) LWS
- Golding's Wood Pasture LWS
- Paddley LWS
- Hallmores area LWS
- St David's Drive Area LWS
- Admirals Walk Lake LWS
- Hoddesdonbury Pasture and Beech Grove LWS
- Lodge Hollow and Spital Brook North LWS
- Hoddesdon Lodge Meadows LWS
- Knowle Thicket by Cock Lane Ford LWS
- Ermine Street N. of Lord Street LWS
- Box Wood (near Hoddesdon) LWS
- Dell's Wood LWS
- Hobbyhorse Wood LWS
- High Wood (near Haileybury College) LWS
- Senior's Lake LWS
- Dalmond's Meadows LWS
- Goldings Wood Ancient Woodland Site (AWS):
- Dells Wood AWS

- Hailey Wood AWS
- Box Wood AWS
- High Wood AWS

The operational controls, emission limits and conditions that we have placed in the permit to protect the above ecological receptors are described in the following sub-sections.

2.1.2 Operational controls

The permit requires the operator to apply the operating techniques identified in table S1.2 of the permit to:

- restrict emissions of polluting substances to air to levels which are insignificant with respect to the above ecological receptors within our screening distance;
- limit production of API under commercial contracts and /or for potential commercial use to the terms of a MPP which has been developed in line with our guidance on MPP (GEH00511BTUN-E-E). This requires the operator to apply a range of techniques identified in the MPP to limit the potential for emissions of potentially polluting substances to within the envelope of assessed emissions for the maximum operational throughput (MOT) included within the application H1 risk assessment (EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5). The techniques include:
 - restrictions to the nature of substances which may be handled or produced on the site i.e.
 - no materials banded Occupational Exposure Band 5 i.e. highly potent (< 0.1 mg/day dose or < 1µg/m³ Occupational Exposure Level) or highly hazardous with respect to European Medicines Agency guidance.
 - restrictions on short and long term use rates for raw materials within both the PRPL facility and the Fleming building to the maximum levels associated with the envelope of assessed emissions for the MOT scenario.
 - restriction on the maximum operational hours for production of API within the facility, to 6272 hours per annum, to reflect the operational scenarios included in the envelope of assessed emissions for the MOT scenario.
 - application of a range of management techniques to ensure:
 - that the risks to ecological receptors (and human health) are assessed and minimised for all proposed production of API through design of:
 - process chemistry
 - process production stages,
 - process controls,
 - emissions abatement techniques,
 - process monitoring, and
 - abatement monitoring to confirm the effectiveness of the techniques.

2.1.3 Emission limits for emissions to air

Table S3.1 of the permit includes limits for emissions of polluting substances to air.

The emission limits for emissions to air from the PRPL facility reflect:

- the waste gas emission limit value of 20 mgC/Nm³ i.e. the limit identified in Annex VII of the IED; and
- the maximum short term and long term emission concentrations for each substance included within the envelope of assessed emissions for the maximum operational throughput (MOT) scenario identified in the MPP.

We have not set emission limit values for emissions to air from the Fleming building and emissions are controlled through the limits on the maximum short and long term consumption rates for certain substances as set out in the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5.

The applicant has demonstrated in the application that the facility falls below the solvent consumption threshold of 50 tonnes per annum for an EPR Schedule 14 solvent emissions activity and the emissions limits values set in Annex VII of the IED are therefore not required for this installation. The applicant has however committed to comply with the Annex VII IED emissions limits in order to demonstrate that their techniques to manage solvents are BAT for the installation.

The applicant has specifically committed to compliance with the waste gas emission limit value of 20 mgC/Nm³ as a 24 hour average of hourly averages and the total emission limit value for fugitive and point source emissions of solvent related VOCs from new installations of 5% of solvent input (with 'input' as defined in Article 57 of the IED) as set out in Annex VII of the IED. The applicant's commitments to operating to these emissions limits are detailed within sections 7.5.2 and 8.3.1.3 of EHS-HOD-001 Hoddesdon Best Available Techniques (BAT) and section 30.2 of the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5. In view of the reliance of the process control systems within the PRPL facility on the continuous emissions monitoring system for VOC emissions and the applicant's commitment to meet the IED limit, we have incorporated this emission limit value into the permit in table S3.1. We have not included the applicant's commitment to meet the total emission limit value as an emission limit within the permit as the IED requires compliance either with the waste gas emission limits or the total mass emission limit to demonstrate BAT. We have however required the applicant to report performance against the 5% total emission limit target on an annual basis.

Compliance with the waste gas emission limit value of 20 mgC/Nm³ as a 24 hour average of hourly averages will be monitored continuously using a continuous emissions monitoring system (CEMS) which meets MCERTS standards for monitoring total carbon emissions from the main PRPL process stack (reference A1). The applicant has not demonstrated that the Flame Ionisation Detector (FID) instrument used within the existing PRPL facility CEMS for monitoring of total VOC emissions to air is MCERTS certified or that operating staff are trained to MCERTS standards for self-monitoring of emissions to air. We have included a pre-operational condition requiring this to be demonstrated before production of API under the MPP (see the pre-operational conditions sub-section of the key issues section).

The short and long term emission levels for each substance included within the envelope of assessed emissions for the maximum MOT scenario identified in the MPP are the relevant short and long term maximum emission concentrations set out in section 23.3 of the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5. The emissions concentrations are those associated with the maximum daily and annual average usage rates for each parameter set out in section 40 of the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5.

We have not included the emission concentrations for API associated with the envelope of assessed emissions within the permit. We have excluded API emissions to air from table S3.1 as there should be no emissions of API to air from the facility. All processes involving handling, transfer or processing of produced API are within enclosed areas with HEPA filtration of extracted air to prevent release. Emissions from the HEPA filtration units in the PRPL facility also undergo water based scrubbing before release to air. Potential API emissions to air were included in the operator's risk assessment at theoretical levels in the absence of any abatement. The calculated unabated emission concentrations were evaluated against environmental quality standards (EQS) for particulate matter with a diameter less than 2.5 micrometres (PM_{2.5}) and screen out as insignificant.

Compliance with these emission concentrations will be by calculation based on the method proposed by the applicant and detailed within section 30 of the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5. As required by Note 4 of table S3.1 of the permit:

- the projected emissions concentrations for each parameter and each API production run are calculated based on this method and values compared with the permit ELVs to confirm the projected emissions are within the envelope of assessed emissions for the MOT scenario; and

- the applicant will perform in-process monitoring of emissions and /or controls in accordance with the MPP notification and approval process to confirm emissions levels are in keeping with projected levels.

We have reviewed the applicant's methodology and agree that this is a reasonable approach to calculating the worst case short and long term emissions levels for each substance under the proposed usage levels. We have checked the applicant's calculations and equations and concur with their findings. We agree that application of this methodology should ensure that concentrations and associated emission rates of each substance cannot exceed the maximum levels and rates included in the envelope of assessed emissions. The notification process required under the MPP condition provides a mechanism for us to review the reliability of the basis of the applicant's methodology.

We have required the operator to deliver an improvement programme to validate the key assumptions made in developing the envelope of assessed emissions for the MPP (see the Improvement programme sub-section of the key issues section).

2.1.4 The multi-product protocol condition

The permit includes the standard MPP condition:

Where the operator proposes to make a change under a multi-product protocol that is not otherwise the subject of an application for approval under the Regulations or this permit:

- the Environment Agency shall be notified of the proposed change;*
- the notification shall contain a description of the change including: an assessment of its environmental impact; any relevant supporting assessments and drawings; and the proposed implementation date;*
- the change shall not be implemented unless approved in writing by the Environment Agency;*
- as from any approved implementation date, the operator shall operate in accordance with the changed multi product protocol in place of the previously approved version.*

This condition requires the operator to have in place management techniques to ensure:

- identification of any proposed production of API which may fall outside of the scope of the MPP and /or the scope of the envelope of assessed emissions before production is commenced
- adherence to a notification process agreed and approved by the Environment Agency to ensure that proposed production of all new API products is assessed and approved by the Environment Agency before production commences.

As previously noted, the notification process required under the MPP condition provides a mechanism for us to review the reliability of the basis of the applicant's methodology. We have included a pre-operational condition requiring the operator to provide in writing the content and format of the notification documentation to facilitate an efficient process for submission, review and approval (see the Pre-operational conditions sub-section of the key issues section). This pre-operational condition also facilitates our ongoing review of the reliability of the basis of the applicant's methodology in that we will have the opportunity to require the operator to submit information regarding projected and actual emissions (which may be based on surrogate measures) for API production runs.

2.2 Emissions to surface water

Discharges to surface water are restricted to clean rain and storm water collected from areas of hardstanding and building roof drainage only. There are seven surface water discharges from the site into Woollens Brook which runs parallel to the east of the site in a southerly direction. Building rainwater drains, roads and hardstanding to the south of the site collected in the surface water storage compound to the southeast of the site with a maximum storage capacity of 890 m³ (W1); the Hilleman and Cafeteria building rainwater drains collected in three storm water collection ponds (W2); the visitor carpark drainage, road drainage for the north and west of the Fleming building and the Fleming building rainwater drains (W3); the Sigal building rainwater drains (W4); the multi-storey carpark drains (W5); the Recycling Centre drainage (W6); and the Cafeteria

roof drains, road drainage from south of the Cafeteria building and the ground around the Archive building (W7). There are isolation valves associated with all release points except for the Sigal building (W4), Recycling Centre (W6) and Archive building area (W7). The isolation valves may be manually activated to prevent discharges in the event of an incident. The car park drains are passed through oil interceptors before mixing with other clean surface water and /or discharge. Uncontaminated surface water collected in bunds and sumps is directed to Woollens Brook by way of the surface water compound with the exceptions of surface waters collected in the Utilities building collection sump, the PRPL External Interceptor Tank Bund and the Recycling Centre bund. Surface water collected in the Utilities building collection sump and the PRPL External Interceptor Tank Bund are transferred to the Trade Effluent system for discharge to sewer. Surface water collected in the Recycling Centre bund is visually inspected before being pumped to Woollens Brook by way of an oil interceptor. The permit includes a pre-operational condition requiring chemical analysis, or other suitable assessment, of this surface water prior to release. Surface waters from the following sumps/bunds are directed, by controlled release following chemical analysis, to the surface water compound: the PRPL general area scrubber compound bund and sump, the PRPL solvent storage compound sump, the PRPL external roadway sump and the Syltherm storage tank bund.

We have assessed the applicant's proposed techniques to prevent contamination of surface waters and are satisfied that there would be no release of pollutants to surface waters from the site. We have required monitoring of oil and grease for emissions to all seven discharge points due to the risk of fugitive emissions of fuel and mechanical oils from vehicle movements on site, the potential for emissions from oil /water interceptors associated with the site car parks and other areas, and the risk of unreported leaks or spills during refuelling of the site bowser and emergency generators.

2.2.1 Ecological receptors for emissions to surface water

Woollens Brook flows in a southerly direction towards the New River approximately 1 km southeast of the site. Woollens Brook joins the New River which flows in a southerly direction. There are no sites of nature conservation, landscape and heritage and/or protected species or habitats identified in the nature conservation screening report as part of the permitting process.

2.2.2 Operational controls

The permit requires the operator to apply the operating techniques identified in table S1.2 of the permit to prevent releases of potentially polluting substances to soil, groundwater and surface waters in the vicinity of the site under normal and abnormal operations.

2.2.3 Emission limits for emissions to surface water

The emission limits for emissions to water (Woollens Brook) from the installation are:

- oil and grease limit: none visible

The oil and grease emission limit has been set for emissions of surface water from all discharge points (W1-W7) as there is the potential for contamination of surface waters released from these points arising from:

- unreported spills of fuel associated with the refuelling of the emergency generators and transfers of fuel to/ from the bowser; and /or
- leaks of fuel or oils from vehicles including emissions from interceptors associated with the site car parks and roadways.

2.3 Emissions to sewer

Discharges to sewer from the permitted activities are restricted by the permit to emissions of trade effluent arising from specific PRPL facility and Fleming building.

Trade effluent generated from the PRPL facility arises from sinks, drains, uncontaminated plant and equipment washings, glassware washing, cooling towers and rainwater from the PRPL facility roof with storage within the two 10 m³ capacity PRPL underground wastewater storage tanks TA1601 and TA1602 located in the sewer interceptor tank area bund identified in drawing HO-B40-00-02 Bunds, sumps and gulleys (submitted 05/03/19) pending pumped transfer to the on-site ETP.

Trade effluent generated from the Fleming building comprises of aqueous waste produced in manufacturing areas from processes including work area cleaning, glassware dishwashing, water consigned to sinks and drains (including plant room drains) and waste water from the purified water system.

All waste water potentially contaminated with process effluents, chemicals and API is separately contained and removed from site as waste water for recovery/disposal. There should be no release of contaminated process effluent to sewer from the installation under normal operations.

We have reviewed the applicant's surface water pollution risk assessment. We have accepted the findings of their assessment that, at their reported discharge flow rates and projected pollutant emission average and maximum concentrations emissions to sewer, emissions are unlikely to have significant impact on the receiving surface waters. We have required monitoring of discharge flow rate, dissolved copper and dissolved zinc in the permit and set limits restricting emissions to levels which do not risk significant impacts on the receiving surface waters.

2.3.1 Ecological receptors for emissions to sewer

The applicant has identified that the trade effluent is discharged to the 150 mm foul sewer located at West Hill Road. The effluent is then received by Rye Meads Sewage Treatment Works (STW) operated by Thames Water and treated using a combination of biological and physical processes before release to surface waters. Rye Meads STW discharge outfall is located at grid reference 539264 209763 and discharges to the River Lee via the Toll House Stream. The discharge enters the River Lee upstream of the Gauging Station at Feildes Weir (Ref. 38001). There are two sites of nature conservation, landscape and heritage and /or protected species or habitats identified in the nature conservation screening report as part of the permitting process:

- Lee Valley Ramsar
- Lee Valley SPA

These sites are approximately 5 km to the south of the Rye Meads STW discharge outfall.

2.3.2 Operational controls

The permit requires the operator to apply the operating techniques identified in table S1.2 of the permit to restrict emissions of polluting substances to sewer to levels which are unlikely to have a significant impact on the receiving surface water.

2.3.3 Emission limits for emissions to sewer

The limits for emissions to sewer from the installation included in table S3.3 of the permit are:

- copper (dissolved): 0.10 mg/l
- zinc (dissolved): 1.60 mg/l
- volume of discharge: 90 m³/day as the annual average of daily averages

We have set the above emission limits based on our review of the applicant's surface water pollution risk assessment (EHS-HOD-007).

The applicant's risk assessment used our H1 tool to derive predicted concentrations (PCs) and predicted environmental concentrations (PECs) in the receiving surface water and screen against the annual average environmental quality standards (AA EQS) for these and other substances. Emissions of all substances except copper, zinc and sulphate screened out as insignificant in Test 1 i.e. release concentrations are less than 10% of the relevant short and/or long term environmental quality standard (EQS). Annual predicted concentrations of zinc and sulphate in the receiving water screened out as insignificant in Test 2 i.e. process contributions (PCs) were less 4% of the AA EQS. The PC for copper of 0.0418 µg/l is 4.18% of the annual average EQS and emissions of copper at the annual average release concentration and average flow rate applied in the applicant's assessment cannot be screened out as insignificant. Whilst not insignificant, the annual average PC for copper screens out at Test stages 3 and 4 as the PC is less than 10% of the EQS and is deemed to be unlikely to cause significant impact. In performing their assessment, the applicant applied:

- their monitored sewer discharge rates for average and maximum daily flow rates in 2018:
 - annual average of daily averages: 72.8 m³/day
 - maximum of daily averages: 100 m³/day.
- the average and maximum concentrations for the range of substances included in the existing Trade Effluent Consent:
 - annual average concentrations based on data from the monthly sewer discharge samples analysed by Thames Water from March 2017:
 - ammonia: 288.3 mg/l
 - sulphate: 800.017 mg/l;
 - zinc: 0.376 mg/l;
 - copper: 0.052 mg/l;
 - sulphide: 0.023 mg/l
 - bromide: 0.868 mg/l
 - phosphorus: 2.482 mg/l
 - maximum concentration based on the limits in the current Thames Water Trade Effluent Consent:
 - ammonia: 35 mg/l
 - sulphate: 1,800 mg/l
 - copper: 3 mg/l
 - zinc: 3 mg/l
 - sulphide: 1 mg/l
 - bromide: 2 mg/l
 - phosphorus: 13 mg/l
 - the appropriate sewage treatment reduction factors (proportion remaining in discharge post activated sludge treatment) from our guidance:
 - ammonia: 0.08
 - sulphate: 1
 - copper: 0.58
 - zinc: 0.33
 - sulphide: 1
 - bromide: 1
 - phosphorus: 0.8

We reviewed the applicant's risk assessment and agree with the findings based on the input data. We note however, that the applicant's risk assessment did not take into account the proposed restriction on operational hours for the facility which we have included within the permitted activities in table S1.1 i.e. 6,272 hrs per annum or maximum of 72% in a year. Taking into account the restricted operational hours, the PC for copper in the receiving water is 0.030 µg/l which is 3% of the AA EQS and screens out as insignificant.

We have conducted our own H1 assessment for projected worst case operating conditions in order to identify appropriate emission limit values for inclusion in the permit at levels which allow discharges of

copper and zinc at the maximum monitored emission levels presented in the applicant's Surface Water Pollution Risk Assessment i.e.:

- zinc:
 - maximum level measured since March 2017 was 1.531 mg/l
 - our H1 assessment level 1.6 mg/l
- copper:
 - maximum level measured since March 2017 was 0.096 mg/l
 - our H1 assessment level 0.1 mg/l

We included emissions of all other substances in our assessment at the maximum existing Trade Effluent Consent limits i.e.:

- ammonia: 35 mg/l
- sulphate: 1800 mg
- sulphide: 1 mg/l
- bromide: 2 mg/l
- phosphorus: 13 mg/l

We applied the sewage treatment reduction factors provided in our guidance and applied a 100% operating mode.

Our assessment highlights that the annual average of daily average discharge volumes must be restricted to 90 m³ per 24 hour period in order to ensure that emissions of copper and zinc at the maximum monitored concentrations do not exceed 10% of the AA EQS. At this flow rate, emissions of all substances at the maximum monitored levels, except zinc and copper, screen out as insignificant i.e. PCs are less than 4% of AA EQS. Emissions of zinc and copper at 1.6 mg/l and 0.1 mg/l respectively, do not screen out as insignificant but will not risk significant impacts on the receiving waters i.e. the projected PCs in the receiving water do not exceed 10% of the AA EQS.

Based on the ELVs set in the permit and on our worst case assessment of continuous emissions at these levels, the total maximum discharge to sewer of dissolved zinc and copper each year will be 52.6 kg and 3.3 kg respectively i.e.:

- for zinc at the ELV of 1.6 mg/l and the maximum volumetric flow rate of 90 m³/day set in the permit, the maximum annual discharge of dissolved zinc is:
 - $1.6 \text{ mg/l} * 90,000 \text{ l/day} * 365 \text{ days/yr} = 52,560,000 \text{ mg/yr} = 52.6 \text{ kg/yr}$.
- for copper at the ELV of 0.1 mg/l and the maximum volumetric flow rate of 90 m³/day set in the permit, the maximum annual discharge of dissolved copper is:
 - $0.1 \text{ mg/l} * 90,000 \text{ l/day} * 365 \text{ days/yr} = 3,285,000 \text{ mg/yr} = 3.3 \text{ kg/yr}$.

Allowing for the relevant sewage treatment reduction factors (0.33 and 0.58 for zinc and copper respectively), the maximum annual discharges of dissolved zinc and copper to the receiving surface waters associated with the sewage treatment works discharge will be 17.4 kg for dissolved zinc and 1.9 kg for dissolved copper. These levels of total annual discharges to surface waters do not exceed the thresholds of 30 kg/yr and 5 kg/yr for zinc and copper respectively for application of the BAT-AELs set out in table 3 the BREF BAT conclusions for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector (CWW) published 30 May 2016 i.e. the CWW BAT conclusions BAT-AELs are not applicable.

Our assessment is based on worst case operating conditions. Under normal operating conditions, we anticipate that pollutant concentrations will be in keeping with the annual average levels included in the applicant's H1 surface water pollution risk assessment (EHS-HOD-007). We have performed our own H1 assessment of the impact of emissions at the annual average concentration for dissolved zinc and copper

reported by the applicant (0.376 mg/l and 0.052 mg/l respectively) at the maximum annual average volumetric flow rate set in the permit (90 m³/day). Our assessment confirms that, taking into account the restriction on operating hours to 6,272 hrs/annum set in the permit, the PCs for dissolved zinc and copper in the receiving waters are 0.153 µg/l and 0.037 µg/l respectively which represent 1.4% and 3.7 % of the annual average EQS for these parameters and screen out as insignificant.

From our assessment, we are satisfied that under normal operating conditions, the impact of emissions of dissolved copper and zinc on the receiving water is likely to be insignificant and that the ELVs set in the permit will ensure that worst case normal operating conditions do not risk significant impacts.

We note that there is no current Maximum Allowable Concentration (MAC) EQS for the pollutants emitted to sewer and emissions of all the screened substances screen out as insignificant at the existing Trade Effluent Consent maximum flow rate of 63 m³/h (17.5 l/s). The discharge volume limit we have set in the permit of 90 m³/day period is greater than the monitored average flow rate in 2018 (72.8 m³/day) and 10% lower than the maximum average daily flow rate monitored in 2018 (100 m³/day).

In conclusion, we consider that the emission limits we have set in the permit allow flexibility for the operator to manage sewer discharge volumes without risk of significant impacts on the receiving waters.

We have required that the operator delivers an improvement programme to ensure that the monitoring of dissolved zinc and copper and the daily average flow rate of the discharge to sewer are undertaken to MCERTS standards (see the Improvement programme sub-section of the key issues section). In view of the low risk of any significant environmental impact we have agreed with the applicant that monitoring may be performed by spot sample rather than requiring 24-hour flow proportional automatic sampling. The operator has stated that they may install flow proportionate sampling and therefore we have added a note to table S3.3 of the permit allowing that sampling arrangements may be changed on agreement with us. We have required that the operator upgrades the existing flow metering to meet our MCERTS standards. We anticipate that the operator may in future be able to use the monitoring data collected to MCERTS standards to demonstrate that worst normal case emissions of zinc and copper are insignificant and may seek to vary the permit to remove the emission limits.

3. Operational control for accident prevention and regulatory reasons relating to the Syltherm XLT heat transfer fluid

The PRPL facility heat transfer system involves the use of Syltherm XLT as a heat transfer fluid. The heat transfer system consists of a bulk storage tank (tank TA1631) for the Syltherm XLT and associated pipework linking the heat transfer fluid to the PRPL facility with an additional loop linking the fluid in tank TA1631 to a refrigeration system located in the Chiller building. The combined capacity of the Syltherm storage tank and supply/transfer lines is 20 m³ i.e. approximately 17 tonnes based on a density of 852 kg/m³ at 25°C (as provided by the applicant). The refrigeration system consists of two chiller packages using R507A as a refrigerant and are each equipped with a single electrically powered compressor, a refrigerant evaporator, an evaporative condenser and a refrigerant surge tank. The banded Syltherm compound and Chiller building are identified in in drawing HO-B40-00-02rev2 – Syltherm & Chiller.

Syltherm XLT is the trade name for the chemical dimethylpolysiloxane. Dimethylpolysiloxane, a silicone polymer is a category 3 flammable liquid with a closed cup flash point of 42°C and vapour pressure of 4 hPa at 25°C. As a category 3 flammable liquid, storage of more than 10 tonnes of this substance at a temperature above the boiling point would require:

- a Hazardous Substances Consent for storage under the Planning (Hazardous Substances) Regulations 2015 and
- the site to be managed as a Tier 1 facility under the Control of Major Accident Hazards (COMAH) Regulations 2015.

The refrigeration process associated with the PRPL heat transfer system is designed to maintain the temperature of the Syltherm XLT fluid in the bulk storage tank TA1631 at -25°C and the system tanks are nitrogen blanketed. The storage temperature of this liquid at -25°C is well below the closed cup flash point for this substance and we agree with the applicant that there is no requirement for a Hazardous Substances

Consent or for the installation to be regulated as a Tier 1 COMAH facility with respect to storage/use of this category 3 flammable liquid.

The applicant has assessed the risk of failure of the refrigerant system which maintains the Syltherm XLT stored temperature at -25°C and concluded failure of the system is unlikely to result in storage at temperatures approaching the flash point. We have accepted the applicant's assessment that the current storage arrangements ensure that the storage of this material minimises the risk of fire or explosion from fugitive emissions of liquid or vapour to an acceptable level. We have identified the EHS-HOD-003 PRPL Heat Transfer System Risk Assessment as an operating technique in table S1.2 of the permit. This requires the applicant to ensure that the temperature of the Syltherm XLT in the bulk storage tank TA1631 must be maintained at -25°C or below, for safety and regulatory reasons.

4.0 Pre-operational conditions

Based on the information in the application, we consider that we need to impose pre-operational conditions. The reasons for imposing the measures and description of the conditions are described in the following sub-sections.

This EPR permit application is for a new bespoke pharmaceutical production facility however the site is an existing site which has been used for many years for pharmaceutical research, development and related non-commercial production. Aspects of site infrastructure have been modified and improved by the applicant since purchasing the site in 2016, in particular the PRPL facility API production modules. Pharmaceutical research and development is currently undertaken on the site in the Fleming building and PRPL facility and supported by the various DAAs included in the permit. We have reviewed the information submitted by the applicant with respect to the existing containment infrastructure, including the recommendations for improvement within the Application Site Condition Report. We are satisfied that the operator will manage their activities to minimise the risk of contamination of soil, groundwater and surface waters but have residual concerns regarding the suitability of certain containment infrastructure for the proposed activities.

Where we consider that infrastructure is unlikely to risk contamination in the short to medium term but requires more detailed assessment and may require improvement to BAT standards as part of a capital investment programme, we have required the improvements detailed in the improvement programme sub-section of the key issues section.

Where we have concerns that the applicant has not adequately demonstrated that existing containment is impermeable, we have set pre-operational measures (or conditions) to ensure actions are taken to provide assurance in the short term.

We have also included pre-operational conditions relating to:

- agreeing the format and content of the MPP notification documentation;
- formalising the daily containment inspections;
- formalising test regimes for surface waters collected in certain sumps;
- management arrangements for notification requirements with respect to incidents;
- demonstration that arrangements for continuous emissions monitoring for the PRPL process stack meet MCERTS standards; and
- the continued suitability of tanks and infrastructure associated with the ETP neutralisation process.

The requirements for these pre-operational conditions are described in more detail in the following sub-sections.

4.1 Notification document format and content to facilitate efficient compliance with the MPP condition (condition 1.5.1).

The applicant proposes to produce up to 250 product runs per annum operating under the MPP within the envelope of assessed emissions. In accordance with condition 1.5.1 of the permit, each run producing new API requires the operator to notify us and obtain our approval before commencing production in the PRPL

facility. We have imposed pre-operational measure 1 to facilitate liaison between the Environment Agency and the operator to develop a system to efficiently manage the notification and approval process.

4.2 Formalising and recording inspection procedures for containment arrangements

Section 7 of the Application Site Condition Report (SCR) includes a number of recommendations based on the findings of the Environmental Risk Assessment (ERA) including a recommendation that the operator formalise existing daily inspections of floors, sumps, bunds, spill trays, pipework and cabinets in process and storage areas, including the solvent store. These checks are to supplement the existing formal, recorded safety and housekeeping inspections. We have imposed pre-operational measure 2 to address this.

4.3 Formalising a procedure for testing of surface waters collected in various sumps prior to discharge to Woollens Brook or the surface water compound.

We have included pre-operational measure 3 which requires the operator to submit, for our review and approval, a procedure to ensure that surface waters collected in the Recycling Centre sump are suitably tested before discharge to Woollens Brook by way of the oil interceptor and discharge reference W6. This pre-operational condition also applies to surface waters collected in the sumps which are released to the surface water compound for discharge to Woollens Brook by way of discharge reference W1.

4.4 Revision to the existing site spill procedure to facilitate compliance with permit conditions 4.3.1 and 4.3.2 regarding notification of accidents or incidents

We have included pre-operational measure 4 which requires the operator to revise their existing site spill procedure (SPT-HOD-0127) in order to facilitate compliance with the wording within permit conditions 4.3.1 and 4.3.2 regarding notification of accidents or incidents which significantly affect or may significantly affect the environment.

4.5 Temporary measures to provide impermeable containment pending delivery of IP1.

We have residual concerns that the applicant has not adequately demonstrated that existing containment within the Winchester Store and the Highly Toxic Hazardous Material Store is impermeable. Pending delivery of IP1, we have set pre-operational measure 5 to ensure measures are taken to provide assurance in the short term.

4.6 Demonstration that the FID instrument used within the PRPL facility CEMS for monitoring of total VOC emissions to air is MCERTS certified and operating staff trained to MCERTS standards for self-monitoring of emissions to air.

Based on the information provided in part 6.1.2 of the document EHS-HOD-002 H1 environmental assessment for the Hoddesdon site H1, we are not satisfied that the applicant's techniques, personnel and equipment for continuous emissions monitoring of VOC emissions from the main PRPL process stack (reference A1) meet MCERTS standards as identified in our guidance available from: www.mcerts.net (in particular M2 monitoring of stack emissions to air and M16 regarding monitoring of VOCs in stack gases). The information provided regarding the Signal 3000HM FID in the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5 and the separate EHS-HOD-004 M1 assessment for Hoddesdon site indicates that the Signal 3000HM FID is not itself an MCERTS certified CEMS FID although the accuracy has been confirmed by tests performed by an accredited organisation. The applicant has also not demonstrated that the personnel involved in the maintenance and use of the existing CEMS are suitably qualified. We have included pre-operational measure 6 to address this.

4.7 Review of continued suitability of containment arrangements prior to re-instatement of the on-site ETP neutralisation process

As detailed in table S1.1 of the permit, the permitted activities include the treatment of trade effluent by neutralisation in the on-site ETP prior to sewer discharge as a Schedule 1 EPR activity S5.4 A1 (a) (ii). The neutralisation process has not been in use for some time and the conditions of the tanks, pipework and containment arrangements require review and may require improvement prior to re-instatement of the process. We have included pre-operational measure 7 to address this requirement.

5.0 Improvement programme

Based on the information in the application, we consider that we need to impose an improvement programme to:

- facilitate the operator's reporting of their baseline monitoring results;
- enable the operator to meet BAT standards for containment infrastructure and monitoring systems improvements which may require capital investment; and
- to adapt management systems to the deliver compliance with specific permit conditions.

We have also included an improvement programme requiring the operator to:

- ensure incoming changes to the availability of a refrigerant fluid will not risk impacts to the functioning of an essential refrigeration process associated with the PRPL heat transfer system.

We have described the improvement programme and the purpose of each requirement in the sub-sections below.

5.1 Improvement relating to reporting of the baseline monitoring results

The applicant carried out baseline monitoring of the site to assess the condition of the soil and groundwater beneath the site prior to purchase of the site in 2016 as part of their due diligence process. On our recommendation, the applicant has committed to performing a more detailed baseline monitoring programme before commencing production of API under the permit. This monitoring is to be performed to our H5 guidance standards. We have included improvement condition 1 to require reporting of the baseline monitoring results and updating of the Site Condition Report.

5.2 Improvements relating to containment arrangements

Where we consider that containment infrastructure is unlikely to risk contamination in the short to medium term but requires more detailed assessment and may require improvement to BAT standards as part of a capital investment programme, we have included improvement conditions 2, 4 and 5.

5.3 Improvement relating to self-monitoring of emissions to water (sewer)

Based on the information provided in the document EHS-HOD-007 surface water pollution risk assessment, the applicant has in place a system for monitoring and recording flow rate for the discharge to sewer but does not currently monitor the chemical composition of emissions to sewer and relies upon monitoring data provided by Thames Water. The permit requires the operator to perform monitoring of dissolved zinc and copper and the daily average volumetric flow to MCERTS standards for monitoring of emissions to water and sewer i.e. the standards identified in our technical Guidance Note (TGN) M18 which describes an overall approach to operator self-monitoring (OSM) and our guidance on minimal requirements for the self-monitoring of flow available from www.mcerts.net. We have included improvement condition 3 to address this.

5.4 Improvement relating to validation of the key assumptions made in development of the envelope of assessed emissions for the MPP

The envelope of assessed emissions has been developed by the applicant on the basis of several key assumptions which are described in section 4.2.2 of the MPP. The assumptions are based on extrapolation of experimental monitoring data for emissions of dichloromethane under a range of typical unit operations to provide emissions levels of the substances included in the envelope of assessed emissions. We have reviewed these assumptions and agree with the operator that the predicted emissions of substances based on this methodology are likely to be conservative i.e. higher than actual emissions under normal worst case operating conditions. We have included improvement condition 6 which requires the operator to validate the key assumptions to provide confidence in the emissions assessment methodology.

5.5 Improvement relating to a review of the Environmental Management System (EMS)

The applicant has developed an Environmental Management System (EMS) which is designed to meet the requirements of ISO14001:2015 as described in section 5 of the document EHS-HOD-001 Hoddesdon Best Available Techniques (BAT). We have included improvement condition 7 to ensure that the operator revises the EMS to facilitate compliance with the conditions within the permit.

5.6 Improvement relating to the incoming change to the availability of R125 refrigerant

In view of the incoming ban on the use of one of the substances currently used as a refrigerant (hydrofluorocarbon (HFC) refrigerant R125 (pentafluoroethane)), we have included improvement condition 8 which requires the operator to develop a plan to manage the effect of the ban. We have required that this plan takes into account the impact of any changes to the refrigeration system on the effectiveness of the refrigeration system in maintaining the Syltherm XLT heat transfer fluid within the bulk storage tank TA1631 at -25°C. The refrigerant fluid system contains a blend of R125 and another lower GWP HFC. As the ban prevents top-up of the system with *virgin* R125, we consider that the ban is unlikely to have an immediate impact. We have allowed 3 months for our approval before the ban is in place.

5.7 Improvement relating to changes to the monitoring locations for discharges of surface water to Woollens Brook

The operator has reported that there are difficulties accessing emission points W1, W6 and W7 where discharges of rainwater collected on-site are made to Woollens Brook. It is therefore not currently possible to visually check for oil and grease directly at these emission points.

The discharge to W1 arises solely from the surface water compound which is accessible and the emission to the brook can therefore be visually checked on a daily basis at the surface water compound. This has been noted in table S3.2 of the permit.

The discharge to W6 arises from surface water collected in the Recycling Centre sump. The operator has previously reported that surface water collected in the Recycling Centre bund is visually inspected before being pumped to Woollens Brook by way of an oil interceptor. The permit includes a pre-operational condition requiring that surface waters collected in the Recycling Centre sump are suitably tested before discharge to Woollens Brook. There is a residual risk of release of oil/grease from the interceptor to this emission point.

The discharge to W7 arises from surface waters collected in the Cafeteria roof drains, road drains from south of the Cafeteria building and the ground around the Archive building. There is a potential for unreported spills during refuelling of the emergency generator located in this area, or leaks from the emergency generator fuel tank, to be emitted to surface water.

In view of the reported lack of access for visual inspection of emission points W6 and W7 we have included improvement condition 9. IP9 requires the operator to submit a written plan for technical assessment and approval by us which details and justifies changes to the monitoring locations identified in table S3.2 of the permit. Pending delivery of IP9 the operator has offered to perform daily visual monitoring of Woollens Brook at a surrogate location downstream of these emission points. This location may be at a point accessed from Paddick Close to the south of the site boundary or other more suitable point closer to the site boundary to be identified by the operator. We have noted this in table S3.2 of the permit.

Decision checklist

Aspect considered	Decision
Receipt of application	
Confidential information	A claim for commercial or industrial confidentiality has not been made.
Identifying confidential information	We have not identified information provided as part of the application that we consider to be confidential.
Consultation	
Consultation	<p>The consultation requirements were identified in accordance with the Environmental Permitting Regulations and our public participation statement.</p> <p>The application was publicised on the GOV.UK website.</p> <p>We consulted the following organisations:</p> <ul style="list-style-type: none"> • Local Authority Environmental Health (Broxbourne Environmental Health) • Health and Safety Executive (HSE) • Local Authority Public Health (Hertfordshire County Council Director of Public Health (DPH)) • Public Health England (PHE) <p>No responses were received from:</p> <ul style="list-style-type: none"> • Local Authority Environmental Health (Broxbourne Environmental Health) • Health and Safety Executive (HSE) • Local Authority Public Health (Hertfordshire County Council Director of Public Health (DPH)) <p>The comments from PHE and our responses are summarised in the consultation section.</p>
Applicant	
Control of the facility	We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the facility after the grant of the permit. The decision was taken in accordance with our guidance on legal operator for environmental permits.
The facility	
The regulated facility	<p>We considered the extent and nature of the facilities at the site in accordance with RGN 2 'Understanding the meaning of regulated facility', Appendix 2 of RGN 2 'Defining the scope of the installation', Appendix 1 of RGN 2 'Interpretation of Schedule 1', guidance on waste recovery plans and permits.</p> <p>The extent of the facilities are defined in the site plan and in the permit. The activities are defined in table S1.1 of the permit and discussed in detail in the</p>

Aspect considered	Decision
	key issues section.
The site	
Extent of the site of the facility	The operator has provided a plan which we consider is satisfactory, showing the extent of the site of the facility. The plan is included in the permit.
Site condition report	<p>The operator has provided a description of the condition of the site, which we consider is not satisfactory. The decision was taken in accordance with our guidance on site condition reports and baseline reporting under the Industrial Emissions Directive.</p> <p>We have advised the operator what measures they need to take to improve the site condition report. The operator has committed to undertaking baseline monitoring of the condition of soil and groundwater under the site and surface water in the vicinity of the site in accordance with our recommendations. The operator has also committed to implementing a regime of regular groundwater and surface water monitoring during the operation of the facility</p> <p>We have included an improvement condition requiring the operator to submit the results of the baseline monitoring to us within 2 months of permit issue.</p> <p>The ERA and the associated documents submitted as part of the Schedule 5(5) notice dated 13/06/19 identified additional information and measures required to ensure that the operation of the facility does not pose risks to controlled waters after the permit has been issued. We have included these additional measures as pre-operational conditions or improvement conditions within the permit (see the key issues section).</p>
Biodiversity, heritage, landscape and nature conservation	<p>The application is within the relevant distance criteria of a site of heritage, landscape or nature conservation, and/or protected species or habitat.</p> <p>We have assessed the application and its potential to affect all known sites of nature conservation, landscape and heritage and/or protected species or habitats identified in the nature conservation screening report as part of the permitting process.</p> <p>The operational controls, emission limits and conditions have been placed in the permit to protect the ecological receptors which are within our screening distance of the site as described in the key issues section.</p> <p>We have not consulted Natural England on the application. The decision was taken in accordance with our guidance.</p>
Environmental risk assessment	
Environmental risk	<p>We have reviewed the operator's assessment of the environmental risk from the facility. The operator's risk assessment is unsatisfactory and required additional assessment by the Environment Agency.</p> <p>The operator's assessment of emissions to air included air dispersion modelling and assessment of the predicted concentrations of emitted substances at sensitive receptors within our screening distance of the facility.</p> <p>The operator's assessment of emissions to air was unsatisfactory as it did not include:</p> <ul style="list-style-type: none"> • an adequate range of elevations for assessment of the impacts on

Aspect considered	Decision
	<p>human health receptors;</p> <ul style="list-style-type: none"> • human health impact assessments against environmental standards for average hourly hydrochloric acid and carbon monoxide concentrations; and • an assessment of nutrient nitrogen or acid deposition at ecological receptors. <p>We reviewed the operator's air emissions risk assessment and performed our own assessment of the above factors.</p> <p>Our assessment shows that, applying the conservative criteria in our guidance on environmental risk assessment, all emissions may be categorised as environmentally insignificant with the exception of the impacts of the following emissions on human health under the worst case maximum operational throughput (MOT) scenario:</p> <ul style="list-style-type: none"> • long term emissions of benzene; • short term emissions of acetic anhydride, acetonitrile, dimethyl sulphate and hydrazine. <p>We have noted that the operator will not be using benzene at the installation and this substance has been included in the assessment technique as a homologue substance to represent emissions of any substances for which no environmental standard or assessment level is available. As a known carcinogen, benzene represents a worst case homologue substance. In the operator's risk assessment benzene was used to represent projected emissions of N-methyl pyrrolidine and trimethylamine.</p> <p>The measures to control emissions of these substances are described in the operating techniques below.</p>
Operating techniques	
General operating techniques	<p>We have reviewed the techniques used by the operator and compared these with the relevant guidance notes and we consider them to represent appropriate techniques for the facility.</p> <p>The operating techniques that the operator must use are specified in table S1.2 in the environmental permit and include our sector guidance note for Speciality Organic Chemicals (SGN 4.02) which reflects the standards for BAT in the European BAT Reference document (BREF) for the Manufacture of Organic Fine Chemicals and our guidance on operating to a multi-product protocol (MPP) guidance note GEH00511BTUN-E-E.</p>
Operating techniques for emissions that do not screen out as insignificant	<p>Emissions of the following pollutants cannot be screened out as insignificant:</p> <p>Emissions to air:</p> <ul style="list-style-type: none"> • long term emissions of benzene (as a homologue substance); • short term emissions of acetic anhydride, acetonitrile, dimethyl sulphate and hydrazine. <p>Our conservative assessment shows that the predicted concentrations (PCs) of the above substances for emissions associated with the MOT scenario exceed the threshold for insignificance at some human health receptors. Our predicted process contributions (PCs) are low and, taking into account</p>

Aspect considered	Decision
	<p>monitored or likely background concentrations, we consider a breach of any environmental standards (ES) for human health at the maximum permitted levels of throughput to be unlikely.</p> <p>As previously noted, the operator will not be using benzene at the installation and benzene represents a worst case homologue substance. In the operator's risk assessment, benzene was used to represent projected emissions of N-methyl pyrrolidine and trimethylamine which have no EQS.</p> <p>We also anticipate that actual short term emissions of acetic anhydride, acetonitrile, dimethyl sulphate and hydrazine will be lower than considered in the assessment as the applicant did not take into account the impact of abatement in the general area scrubber or the dedicated reactor scrubbing systems on projected emissions from the PRPL facility. Use of these abatement plant and in-process monitoring to check performance of abatement plant is required under the operator's MPP.</p> <p>The permit requires the operator to apply the operating techniques identified in table S1.2 of the permit (the key issues section).</p> <p>Emissions to water (sewer):</p> <ul style="list-style-type: none"> • Zinc (dissolved) • Copper ((dissolved) <p>Under our conservative assessment of worst case emissions associated with emissions to sewer at the maximum permitted levels and volumetric flow, the PCs for dissolved zinc and copper in receiving surface waters are not insignificant but are unlikely to have significant impacts. The operating techniques proposed to control and minimise emissions of zinc and copper to sewer are discussed in the key issues section.</p> <p>We have assessed whether the proposed techniques are BAT.</p> <p>The proposed techniques /emission levels for emissions that do not screen out as insignificant are in line with the techniques and benchmark levels contained in the technical guidance and we consider them to represent appropriate techniques for the facility. The permit conditions ensure compliance with relevant BREF and ELVs deliver compliance with BAT-AELs.</p>
<p>Operating techniques for emissions that screen out as insignificant</p>	<p>Emissions of the following pollutants have been screened out as insignificant, and so we agree that the operator's proposed techniques are BAT for the installation.</p> <p>Emissions to air:</p> <ul style="list-style-type: none"> • Acetone • 1,2-Dibromoethane • 1,2-Dichloroethane • 1,2-dimethoxyethane • 1,4-Dioxane • 2-Methyltetrahydrofuran • Acrylic acid

Aspect considered	Decision
	<ul style="list-style-type: none"> • Acrylonitrile • Allyl Alcohol • Ammonia • Aniline • *Active Pharmaceutical Ingredients (API) • Benzyl chloride • Bromine • Butane • Carbon monoxide • Dichloromethane • Dimethylformamide • Ethanol • Ethyl Acetate • Ethyl Acrylate • Formaldehyde • Hydrochloric acid • Hexane • Isopropyl Acetate • Methanol • Methyl Ethyl Ketone • Methyl tertiary butylether • n-Heptane • Nitric Acid • N-methylpyrrolidine • Orthophosphoric acid • Phosgene • Particulate Matter (PM) • Propan-1-ol • Propan-2-ol • Sodium hydroxide • Styrene • Tetrahydrofuran • Toluene • Triethylamine • Vinyl acetate

Aspect considered	Decision
	<ul style="list-style-type: none"> • Noise and vibration <p>Emissions to water (sewer):</p> <ul style="list-style-type: none"> • Ammonia • Bromide • Phosphorus • Sulphate • Sulphide • Sulphate <p>We consider that the emission limits included in the installation permit reflect the BAT for this installation.</p>
Permit conditions	
Use of conditions other than those from the template	Based on the information in the application, we consider that we do not need to impose conditions other than those in our permit template.
Raw materials	<p>We have specified limits and controls on the use of raw materials and fuels by way of the operating techniques included in table S1.2 of the permit rather than table S2.1</p> <ul style="list-style-type: none"> • With respect to handling and production of API: <ul style="list-style-type: none"> ○ by way of the MPP operating technique, the permit requires that no materials are to be used/produced/stored on-site that are banded Occupational Exposure Band 5 i.e. highly potent (< 0.1 mg/day dose or < 1µg/m³ Occupational Exposure Level) or highly hazardous with respect to European Medicines Agency guidance. This is in keeping with the operator's proposed limitations on the nature of API which will be produced within the facility. • With respect to the Syltherm XLT heat transfer fluid used in the PRPL heat transfer system: <ul style="list-style-type: none"> ○ by way of the EHS-HOD-003 PRPL Heat Transfer System Risk Assessment operating technique the permit requires that the temperature of the Syltherm XLT in the bulk storage tank TA1631 must be maintained at, or below -25°C. This is discussed in more detail in the key issues section. • With respect to consumption of raw materials which have the potential to be emitted to air during use: <ul style="list-style-type: none"> ○ by way of the MPP and associated EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5 operating techniques the permit requires that usage levels must not exceed the maximum short term and long term use rates for raw materials associated with the MOT scenario. The projected emissions from use of each raw material in the MOT scenario form the basis of the envelope of assessed emissions for the installation described in the MPP and the associated EHS-HOD-002 H1 Environmental Assessment for

Aspect considered	Decision
	Hoddesdon V5. The maximum use rates for raw materials used in the PRPL facility and the Fleming building are as listed for the MOT scenario in tables 32 and 33 of the EHS-HOD-002 H1 risk assessment. The limits for the PRPL facility are reproduced in Tables 1 and 2 of the MPP.
Pre-operational conditions	Based on the information in the application, we consider that we need to impose pre-operational conditions. The reasons for imposing the conditions and description of the conditions are described in the key issues section.
Improvement programme	Based on the information on the application, we consider that we need to impose an improvement programme. We have described the improvement programme and the purpose of each requirement in the key issues section.
Emission limits	<p>ELVs or maximum calculated emissions concentrations have been set for the following substances as described in the key issues section</p> <p>Emissions to air:</p> <ul style="list-style-type: none"> • Acetic anhydride • Acetone • Acetonitrile • 1,2-Dibromoethane • 1,2-Dichloroethane • 1,2-dimethoxyethane • Dimethyl sulphate • 1,4-Dioxane • 2-Methyltetrahydrofuran • Acrylic acid • Acrylonitrile • Allyl Alcohol • Ammonia • Aniline • Active Pharmaceutical Ingredients (API) • Benzene • Benzyl chloride • Bromine • Butane • Carbon monoxide • Dichloromethane • Dimethylformamide

Aspect considered	Decision
	<ul style="list-style-type: none"> • Ethanol • Ethyl Acetate • Ethyl Acrylate • Formaldehyde • HCl • Hexane • Hydrazine • Isopropyl Acetate • Methanol • Methyl Ethyl Ketone • Methyl tertiary butylether • n-Heptane • Nitric Acid • N-methylpyrrolidine • Orthophosphoric acid • Phosgene • Particulate Matter (PM) • Propan-1-ol • Propan-2-ol • Sodium hydroxide • Styrene • Tetrahydrofuran • Toluene • Triethylamine • Vinyl acetate • Volatile Organic Compounds (VOC) <p>Emissions to sewer:</p> <ul style="list-style-type: none"> • Zinc • Copper • Volume of discharge <p>For emissions to air, we have imposed stricter ELV or maximum calculated emission concentrations than those identified as BAT benchmark levels in our sector guidance EPR 4.02. We have imposed limits for substances other than VOCs which are at the calculated maximum emissions values for each emissions point included in the envelope of assessed emissions for the MOT operating scenario. The operator must demonstrate to us that these limits will be met for each proposed new API production run or campaign of API.</p>

Aspect considered	Decision
	<p>Demonstration that the limits will be met is to be by calculation based on the methodology set out in the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5. The operator will provide this demonstration to us by way of the notification process required under the MPP.</p> <p>The ELV or maximum calculated emission concentrations for emissions to air included in the permit have been proposed by the operator and accepted by us and are to be met through a combination of techniques described in the key issues section, including limiting use of the associated materials to the maximum use rates for raw materials used in the PRPL facility and the Fleming building as listed for the MOT scenario in tables 32 and 33 of the EHS-HOD-002 H1 risk assessment. The maximum use rates for the PRPL facility are reproduced in Tables 1 and 2 of the MPP.</p> <p>For emissions of VOC to air, we have applied a limit which is in keeping with BAT identified in Chapter V and Annex VII of the Industrial Emissions Directive 2010/75/EU (IED) for manufacture of pharmaceutical products. The operator has demonstrated that the installation falls below the threshold of solvent use that requires this emission limit to be applied but has proposed and committed to maintain compliance with this limit in order to demonstrate that their management of solvent emissions meets BAT for manufacture of pharmaceutical products.</p> <p>For emissions to sewer, we have imposed ELVs which reflect the maximum monitored levels for dissolved zinc and copper since March 2017 as reported by the operator. At the maximum discharge volume set in the permit of 90 m³ per day (as an annual average of daily averages), the ELVs ensure that under worst case operating conditions, emissions of dissolved zinc and copper to sewer will not risk significant impacts in receiving waters. As noted in the key issues section, the BAT-AELs for direct emissions of zinc and copper to a receiving water body described in table 3 of the BREF BAT conclusions for Common Waste Water and Waste Gas Treatment/management Systems in the Chemical Sector (CWW) published 30 May 2016 are not applicable as the worst case emissions of these metals to surface waters do not exceed the relevant thresholds of 30 kg/yr and 5 kg/yr respectively.</p> <p>The ELV and maximum calculated emission concentrations we have set in the permit reflect BAT for this installation.</p>
Monitoring	<p>We have decided that monitoring should be carried out for the parameters listed in the permit, using the methods detailed and to the frequencies specified.</p> <p>These monitoring requirements have been imposed in order to provide evidence of compliance with BAT standards described in the:</p> <ul style="list-style-type: none"> • sector guidance EPR 4.02, which reflects the BAT standards in the BREF for the Manufacture of Organic Fine Chemicals; • Annex VII of the IED regarding emissions of VOCs from manufacture of pharmaceutical products; • the operator's MPP for production of API in the PRPL facility which reflects the BAT standards in our guidance on MPP GEHO0511BTUN-E-E.

Aspect considered	Decision
	<p>We made these decisions in accordance with our sector guidance EPR 4.02 and our MPP guidance GEHO0511BTUN-E-E.</p> <p>Based on the information in the application, we are not fully satisfied that the operator's techniques, personnel and equipment have either MCERTS certification or MCERTS accreditation as appropriate. We have imposed a pre-operational measure regarding monitoring of emissions to air from the PRPL facility process stack and an improvement condition regarding monitoring of emissions to sewer to address our concerns. The reasons for the pre-operational measure and improvement condition are described in the key issues section.</p>
Reporting	<p>We have specified reporting in the permit.</p> <p>We have required reporting of monitoring data for emissions to air and water (surface and sewer) every 6 months. Annual reporting of emissions to air and 6 monthly reporting of emissions to water are the normal reporting frequencies set out in our permit template for the chemicals sector.</p> <p>We have required the increased reporting frequency for emissions to air in order to facilitate our review of the operator's ability to comply with the permit conditions. We have noted in the permit that this reporting frequency applies unless otherwise agreed in writing with us. We anticipate that the reporting frequency for emissions to air will reduce to annual reporting if the operator demonstrates compliance.</p> <p>We have required reporting of the following production and performance parameters annually:</p> <ul style="list-style-type: none"> • annual production of API (total); • annual water usage; • annual energy usage; • solvent consumption as defined in Article 57 of the IED; and • solvent fugitive emissions as defined in Article 57 of the IED <p>Annual reporting of these parameters is the normal reporting frequency set out in our permit template for the chemicals sector.</p> <p>We have required the reporting of other performance parameters on a more frequent (monthly) basis for the first year and quarterly thereafter on agreement with us:</p> <ul style="list-style-type: none"> • average and maximum VOC emission levels (expressed as carbon) from PRPL process stack • solvent usage in accordance with MPP annual and short term limits with split for PRPL and Fleming building usage • inorganic reagent usage in accordance with MPP annual and short term limits with split for PRPL and Fleming building usage <p>We have required this increased reporting frequency to enable us to monitor the operator's ability to comply with the restrictions on emissions of VOCs and other substances associated with the envelope of assessed emissions as defined in the MPP. The envelope of assessed emissions is based on calculated emissions rates associated with raw material consumption rates</p>

Aspect considered	Decision
	<p>for the activities in both the PRPL facility and the Fleming building as defined in the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5. The permit requires the operator to assess and report on a monthly basis the consumption of each reagent in tonnes and as a percentage of the maximum short and long term consumption limit per reagent per facility.</p> <p>We anticipate that the monthly reporting frequency for these performance parameters will reduce as the operator demonstrates their ability to maintain compliance with emissions and raw material usage rate limitations.</p> <p>We made these decisions in accordance with our typical reporting frequencies set out in our template permit for the chemicals sector and our guidance regarding MPP (GEHO0511BTUN-E-E).</p>
Operator competence	
Management system	<p>There is no known reason to consider that the operator will not have the management system to enable it to comply with the permit conditions.</p> <p>The decision was taken in accordance with the guidance on operator competence and how to develop a management system for environmental permits.</p>
Relevant convictions	<p>The Case Management System has been checked to ensure that all relevant convictions have been declared.</p> <p>No relevant convictions were found. The operator satisfies the criteria in our guidance on operator competence.</p>
Financial competence	<p>There is no known reason to consider that the operator will not be financially able to comply with the permit conditions.</p>
Growth Duty	
Section 108 Deregulation Act 2015 – Growth duty	<p>We have considered our duty to have regard to the desirability of promoting economic growth set out in section 108(1) of the Deregulation Act 2015 and the guidance issued under section 110 of that Act in deciding whether to grant this permit.</p> <p>Paragraph 1.3 of the guidance says:</p> <p>“The primary role of regulators, in delivering regulation, is to achieve the regulatory outcomes for which they are responsible. For a number of regulators, these regulatory outcomes include an explicit reference to development or growth. The growth duty establishes economic growth as a factor that all specified regulators should have regard to, alongside the delivery of the protections set out in the relevant legislation.”</p> <p>We have addressed the legislative requirements and environmental standards to be set for this operation in the body of the decision document above. The guidance is clear at paragraph 1.5 that the growth duty does not legitimise non-compliance and its purpose is not to achieve or pursue economic growth at the expense of necessary protections.</p> <p>We consider the requirements and standards we have set in this permit are reasonable and necessary to avoid a risk of an unacceptable level of pollution. This also promotes growth amongst legitimate operators because</p>

Aspect considered	Decision
	the standards applied to the operator are consistent across businesses in this sector and have been set to achieve the required legislative standards.

Consultation

The following summarises the responses to consultation with other organisations, our notice on GOV.UK for the public and the way in which we have considered these in the determination process.

Responses from organisations listed in the consultation section

Response received from
Public Health England, Centre for Radiation, Chemical and Environmental Hazards, received on 20/08/18
Brief summary of issues raised
<p>Public Health England made the following recommendations:</p> <ul style="list-style-type: none">• Any Environmental Permit issued for this site should contain conditions to ensure that the following potential emissions do not impact upon public health: emissions to air from point and fugitive sources for example, nitrogen dioxide (NO₂), volatile organic compounds (VOCs) and other organic and inorganic compounds; and emissions to water from activities on site;• The Environment Agency (EA) may also wish to consider the need for a specific Accident Management Plan that includes the risk of fires to prevent significant off site impact; and• In relation to potential risk to public health, the EA should also consult the following relevant organisation(s) in relation to their areas of expertise: the local authority for matters relating to impact upon human health of contaminated land; noise, odour, dust and other nuisance emissions; the Food Standards Agency, where there is the potential for deposition on land used for the growing of food crops or animal rearing; and the Director of Public Health for matters relating to wider public health impacts. <p>PHE stated:</p> <p>‘Based solely on the information contained in the application provided, PHE has no significant concerns regarding risk to health of the local population from this proposed activity, providing that the applicant takes all appropriate measures to prevent or control pollution, in accordance with the relevant sector technical guidance or industry best practice.’</p>
Summary of actions taken or show how this has been covered
<p>We have taken into consideration point source and fugitive emissions to air in our determination of this new bespoke application and are satisfied that the operating techniques employed, which are in line with appropriate sector and BAT guidance, and the conditions set in the permit prevent risk of significant impact on public health. We have audited the operator’s air emissions impact assessment including the air dispersion model as described in the key issues section.</p> <p>The operator has provided a specific Accident Management Plan for the site that includes risk of fires and has described the proposed measures to minimise the potential for major accidents including fire. We are satisfied that the proposed measures to minimise and mitigate the risk of fires and other major accidents are in line with appropriate sector and BAT guidance.</p> <p>We consulted Broxbourne Environmental Health and Hertfordshire County Council Director of Public Health during the determination of this permit application. We did not receive any representations from these organisations. We did not consult the Food Standards Agency as there is no likelihood of emissions from the installation impacting on the food chain.</p>